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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,012	05/29/2001	Chaitan Khosla	300622000212	9415

25225 7590 09/22/2005
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,012

Applicant(s)

KHOSLA ET AL.

Examiner

David J. Steadman

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] The finality of the rejection of the last Office action is withdrawn. According to MPEP 706.07(d), "if ... the primary examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection." In view of the reinstated enablement rejection as set forth below, the instant Office action is a non-final Office action.

[3] Claims 19 and 24-26 are pending in the application.

[4] Applicants' response, filed on 8/24/2005, to the Office action mailed on 4/21/2005, is acknowledged.

[5] Applicants' arguments filed on 8/24/2005 have been fully considered.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Specification/Informalities

[7] Applicants should indicate the filing date of priority application 09/434,289 in applicants' claim for domestic priority in the first paragraph of the specification. See particularly the amendment to the specification filed 4/21/2003.

Claim Rejections - 35 USC § 112, First Paragraph

[8] The new matter rejection of claim 26 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' arguments and upon further consideration of the rejection.

[9] The new matter rejection of claims 19 and 24-25 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the first paragraph of Example 4 indicates that applicants are testing whether post-translational processing in *S. erythraea* will be effective with "unnatural substrates," which according to applicants, is interpreted as modified forms of 6-dEB. Applicants argue the meaning of "unnatural substrates" is clearly intended to be those forms of 6-dEB other than the natural starter unit, *i.e.*, those having a substituent at position 13 other than methyl or ethyl. According to applicants, this is clear from the specification at p. 3, lines 3-6, which states (in relevant part), "[a]ccordingly, it would be advantageous to provide a mutant form of the modular polyketide synthesis system which cannot employ the natural starter unit. Such systems can be induced to make novel polyketides by supplying, instead, a suitable diketide as an NAC thioester or other suitable thioester."

Applicants' argument and showing of support for "unnatural substrates" as meaning 6-dEB having a substituent at position 13 other than methyl or ethyl is not found persuasive. However, while it is acknowledged that the specification discloses that "[t]he DEBS system in particular has been shown to accept non-natural primer

units” and “it has become clear that... such unnatural substrates can be utilized” (p. 2, bottom), there is no explicit or implicit disclosure in the specification that 6-dEB having methyl or ethyl at position 13 is the natural primer or starter unit of the *S. erythraea* DEBS, including *S. erythraea* strain A34 DEBS, as asserted by applicants. It is suggested that applicants provide evidence that the natural primer unit of the *S. erythraea* DEBS, including *S. erythraea* strain A34 DEBS, is 6-dEB having methyl or ethyl at position 13.

Applicants argue the reason that strain A34 was used in Example 4 instead of wild-type *S. erythraea* was to eliminate complications and for convenience in testing – not because the mutant is expected to be particularly effective.

Applicants' argument is not found persuasive. MPEP § 2163 states, “when filing an amendment an applicant should show support in the original disclosure for new or amended claims” and “[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description.” Thus, regardless of the reason(s) why strain A34 was employed in Example 4, applicants should show support for the claimed methods. It is evident from the prosecution history that applicants point to Example 4 of the specification (pp. 8-9) as showing support for the claimed method. While the examiner *can* find support for the embodiment of claim 26, the original application fails to disclose support – either explicit or implicit – for the method of claims 19 and 24-25. Applicants are requested to show support for a method of converting an unglycosylated 6-dEB as

encompassed by the claims to a glycosylated form thereof and extracting that glycosylated form from the culture medium using *any* strain of *S. erythraea*.

[10] Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection was raised (Office action mailed 12/3/2002) and subsequently withdrawn (Office action mailed 2/18/2004) in view of applicants' cancellation of claims reciting "strain A34." However, as claims 25-26 have been added back in the amendment filed 1/28/2005, the rejection is reinstated.

The invention appears to employ a mutant strain of *S. erythreus* NRRL 2338 generated using UV radiation as taught by the reference of Weber et al. (*J. Bacteriol* 164:425-433). There is no indication in the reference of Weber et al. that the strain was deposited with a recognized public repository for biological material. Further, the method used to create the mutant strain creates random genetic alterations and the mutations within the *S. erythreus* chromosome that resulted from the UV irradiation are not described in Weber et al. Since the strain is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The mutations within the *S. erythreus* strain are not fully disclosed, nor has the strain shown to be publicly and freely available. The enablement requirement of 35 U.S.C. § 112 may be satisfied by a deposit of the recited strain.

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Neither the specification nor the prior art discloses a repeatable process to obtain the strain and it is not apparent if the strain is readily available to the public. Accordingly, it is deemed that a deposit of the strain should have been made in accordance with 37 CFR 1.801-1.809.

If a deposit of the strain has been made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;
2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become inviable.

Conclusion

[11] Status of the claims:

Claims 19 and 24-26 are pending.


Claims 19 and 24-26 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656